PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	12 JAN 2006
Applicant's or agent's file reference 2329-00150	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/27216	29 July 2005	29 July 2004

International Patent Classification (IPC) or both national classification and IPC
IPC(8): A61B17/32; US: 606/079, 167, 182, 183

Applicant X-STEN

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	29 November 2005	Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2005)

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	7-9, 18-39	YES
	Claims	1-6, 10-17	NO
Inventive step (IS)	Claims	7-9, 23-27, 32, 33, 35, 36, 38, 39	YES
	Claims	1-6, 10-22, 28-31, 34, 37	NO
Industrial applicability (IA)	Claims	1-39	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-6 and 10-16 lack novelty under PCT article 33(2) as being anticipated by US Patent No. 6,746,451 to Middleton, herein after referred to as Middleton.

Referring to claims 1-2, Middleton discloses a tissue cavitation device (such as 100, 600, etc.) including an occluding member (such as 620, and other corresponding components for other embodiments) with a cutting device (130, 630, etc.) on the distal end for the cutting of tissues around the distal end of an introducing device such as a cannula (such as 14, etc.). The cannula is capable of tissue penetration, as recited in column 5, lines 25-40. See also (Col. 3, line 13-16). The device structure will engage the tissue when inserted and resect the tissue. Middleton also discloses a two phase tissue engaging device, wherein said device expands (120, 111, etc.) when leaving the distal end of the introducing device engaging the tissues that surround the distal end of the cannula, said two phase device being a trochar, cannula or needle. (Col. 3 line 16-34; Col. 6, ln 11-18).

Referring to claims 3-4, Middleton discloses that as applied to claim 1 as well as a tissue cutting device that has a rotatable or reciprocal shaft (Col. 3, line 30-33)

Referring to claims 5, 10 and 14, Middleton discloses that as applied to claim 1, as well as a tissue cavitation device including an occluding member on the distal that has a two phase tissue engaging device wherein the device is in a normal or retracted position when adjacent to the distal end and extends when removed. (Col. 6, line 11-29)

Regarding claim 6, Middleton discloses that as applied to claim 1, as well as tissue removal means for retrieving the tissue, as recited in column 11, lines 21-29.

Referring to claim 11-12, Middleton further discloses that as applied to claim 10, as well as a cutting device that could utilize serrated edges, threads, cutting flutes, abrasive surfaces, and beveled edges and various combinations. (Col 7, line 27-31)

Referring to claim 13, Middleton discloses that as applied to claim 10 as well as a cutting device that could be slidably connected to the shaft of the cannula (Col 11. line 32-35).

Referring to claims 14-16, Middleton discloses that as applied to claim 10, as well as a tissue cavitation device that can be used for tissue harvesting, the removal of diseased hard or soft tissues, or the general removal of hard or soft tissues. (Abstract, Col. 3, line 5-12)

Claim 17 lacks novelty under PCT article 33(2) as being anticipated by US Patent No. 6,010,493 to Snoke, herein after referred to as Snoke.
Referring to claim 17, Snoke discloses percutaneously accessing the epidural space and introducing a fluid to distend the epidural space to aid in a variety of diagnostic and therapeutic procedures, including the introducing of a cutting or tissue removal tool. (Abstract, Fig 13, Col 2. line 21-25 & 39-46, Col. 4, line 11-15, Col. 4, line 44-54, claim 3)

Claims 18-22 lack an inventive step under PCT article 33(3) as being obvious over Snoke in view of Middleton.
Regarding claim 18, Snoke discloses that as applied to claim 17. However, Snoke does not recite the specifics of the cutting tool where the cutting tool has an occluding member slidably received on or in a cannula where an aperture is closed when the occluding member is adjacent the cannula distal end. On the other hand, Middleton discloses a cutting device for cutting tissues adjacent to the distal and of a cannula, said cutting device being slidably connected to the shaft of said cannula, as discussed above with regard to claim 1. See also (Col. 3, line 13-34, Col 11, line 32-35). Therefore, it would be obvious to one of ordinary skill in the art to utilize the cutting system of Middleton to perform the method of Snoke for the purpose of proper tissue removal.

Regarding claim 19, Snoke as modified by Middleton disclose that as applied to claim 18. Further Middleton discloses means for tissue removal as discussed above with regard to claim 6 as in column 11, lines 21-29. Therefore, it would be further obvious in the modification of Snoke to include tissue removal means, as taught by Middleton for the purpose of retrieving the tissue and removing it after excision.

See supplemental box

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-Box V-

Referring to claim 20, Snoke as modified by Middleton discloses that as applied to claim 17. Further, Middleton discloses the removal of tissues as described in reference to claims 1 and 10, but does not disclose providing a working zone as in claim 17. Snoke discloses percutaneously accessing the epidural space and introducing a fluid to distend the epidural space as discussed in reference to claim 17 (Abstract, Fig 13, Col 2. line 21-25 & 39-46, Col. 4, line 11-15, Col. 4, line 44-54, claim 3). It would be obvious to one skilled in the art to access the epidural space in accordance with Snoke and excise the tissues using the device and method described by Middleton for the purpose of enhanced tissue removal and spinal stenosis treatment.

Referring to claims 21 and 22, Snoke as modified by Middleton discloses that as applied to claim 20 as well as Middleton also discloses a device for cutting multiple types of tissues, including soft tissue and bone. (Abstract, Col 10, line. 46-48). Therefore, it would be further obvious in the modification to include cutting multiple types of tissues, including soft tissue and bone. Further, in the modification the procedure is capable of being carried out without repositioning the device.

Claims 28 -31, 34 and 37 lack an inventive step under PCT article 33(3) as being obvious over Snoke in view of Middleton and further in view of 4,994,072 to Bhate, herein after referred to as Bhate.
Regarding claim 28, Snoke discloses a method of treating a stenosis in a spine via percutaneous access of the epidural space, as discussed with regard to claim 17. Snoke also discloses tissue removal but is silent as to the specifics of the tissue removal device. Middleton, on the other hand, discloses a tissue removal tool as discussed with regard to claim 1. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to include the expandable cutting device as disclosed by Middleton in the spinal procedure of Snoke for the purpose of enhanced tissue removal. Further, it would be obvious to have this be in a kit for procedural kits are well known in the art.

Regarding claims 29 and 30, Snoke as modified by Middleton disclose that as applied to claim 28. However, Snoke and Middleton are silent on the use of a contrast medium. On the other hand, Bhate discloses an expandable dilation catheter or cannula in which the expansion fluid is a radiopaque fluid contrast medium that is introduced. It would be obvious to one skilled in the art to further modify the invention of Snoke as modified by Middleton to include accessing the epidural space with the use of the contrast medium as disclosed in Bhate for purpose of enhanced imaging as it is well known that the introduction of a contrast medium is useful in the aid of imaging procedures within the body. Regarding claim 30, a non-ionic myelographic contrast medium would be further obvious to one of ordinary skill in the art as it is a well known contrast medium.

Regarding claim 31, Snoke as modified by Middleton and further by Bhate disclose that as applied to claim 28. Further, a volume of medium that is injectable at ambient temperatures and more viscous at body temperature would further be obvious to one of ordinary skill in the art at the time of invention for purpose of enhanced visualization and better fluid handling ability once inside the body.

Regarding claim 34, Snoke as modified discloses that as applied to claim 28. Further, Snoke discloses a surgical device such as that shown in block 141.

Regarding claim 37, Snoke as modified discloses that as applied to claim 34. Further, Middleton shows a barbed member (such as 130). Therefore, the cutting member would be obvious in the modification.

Claims 7-9 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a means for resecting and removing tissue comprising a keyhole slot, with a hook comprising a length of wire bent through at least 270 degrees.

Claims 23-27 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the combination of limitations recited in claim 20 including anchoring a tissue extracting device in the ligamentum flavum to pull said ligament into the desired position and using a second anchoring device to retain the ligamentum flavum in the desired position. Claims 24-27 depend from claim 23.

Claims 32 and 33 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach of fairly suggest the limitations of claim 28 including utilizing a contrast medium containing a bioactive agent or a steroid

Claim 35 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the combination of limitations of claim 34 including a cannulated scalpel having a side aperture proximal its distal end, comprising two radially extendable arms constructed such that radially extending arms causes them to extend outward through said side aperture and retracting said arms causes them to close through said aperture.

Claim 36, 38 and 39 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the combination of limitations disclosed in claim 34 including a surgical device comprising a tool for resecting a section of the ligamentum flavum; surgical device for engaging and retracting the ligamentum flavum and means for anchoring the retracted ligamentum flavum.

Claims 1-39 meet the criteria as set forth in PCT Article 33(4) because the claimed subject matter can be made and/or used in industry.